

§ 250.101

(b) Therefore, amyl nitrite inhalant will be regarded as misbranded unless the labeling on or within the package from which the drug is to be dispensed bears adequate information for its safe and effective use by physicians, in accordance with § 201.100(c) of this chapter, and its label bears the legend “Caution: Federal law prohibits dispensing without prescription.”

(c) Regulatory proceedings may be initiated with regard to the interstate shipment of amyl nitrite inhalant that is labeled, advertised, or dispensed contrary to this statement of policy if such act occurs after July 1, 1969.

EFFECTIVE DATE NOTE: At 67 FR 4906, Feb. 1, 2002, § 250.100 was amended in paragraph (b) by removing the phrase “legend ‘Caution: Federal law prohibits dispensing without prescription.’” and by adding in its place the phrase “statement ‘Rx only.’”, effective April 2, 2002.

§ 250.101 Amphetamine and methamphetamine inhalers regarded as prescription drugs.

(a) Recurring reports of abuse and misuse of methamphetamine (also known as desoxyephedrine) inhalers show that they have a potentiality for harmful effect and that they should not be freely available to the public through over-the-counter sale. From complaints by law-enforcement officials, health officials, individual physicians, parents, and others as well as from Food and Drug Administration investigations, it is evident that the wicks from these inhalers are being removed and the methamphetamine they contain is being used as a substitute for amphetamine tablets. Amphetamine tablets and amphetamine inhalers have been restricted to prescription sale because of their potentiality for harm to the user.

(b) It is the considered opinion of the Food and Drug Administration that, in order to adequately protect the public health, inhalers containing methamphetamine or methamphetamine salts (d-desoxyephedrine, or dl-desoxyephedrine, or their salts), as well as amphetamine inhalers should be restricted to prescription sale and should be labeled with the legend “Caution: Federal law prohibits dispensing without prescription.”

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§ 250.102 Drug preparations intended for human use containing certain “coronary vasodilators”.

(a)(1) The Food and Drug Administration finds that the following “coronary vasodilators” are extensively regarded by physicians as safe and useful as employed under medical supervision for the management of angina pectoris in some patients:

Amyl nitrite.
Erythrityl tetranitrate.
Mannitol hexanitrate.
Nitroglycerin.
Potassium nitrite.
Sodium nitrite.

(2) Additionally, new-drug applications have been approved for products containing:

Inositol hexanitrate.
Isosorbide dinitrate.
Octyl nitrite.
Pentaerythritol tetranitrate.
Triethanolamine trinitrate biphosphate
(trolnitrate phosphate).

(b) The Food and Drug Administration also finds that there is neither substantial evidence of effectiveness nor a general recognition by qualified experts that such drugs are effective for any of the other purposes for which some such drugs are promoted to the medical profession in labeling and advertising. In particular, neither clinical investigations nor clinical experience justify any representations that such drugs are effective in the management of hypertension; in the management of coronary insufficiency or coronary artery disease, except for their anginal manifestations; or in the management of the post coronary state, except angina pectoris present after coronary occlusion and myocardial infarction.

(c) Any preparation containing such drugs that is labeled or advertised for any use other than management of angina pectoris, or that is represented to be efficacious for any other purpose by reason of its containing such drug, will

be regarded by the Food and Drug Administration as misbranded and subject to regulatory proceedings, unless such recommendations are covered by the approval of a new-drug application based on a showing of safety and effectiveness.

(d) Any such drug in long-acting dosage form is regarded as a new drug that requires an approved new-drug application before marketing.

(e) Any of the drugs listed in paragraph (a)(2) of this section is regarded as a new drug that requires an approved new-drug application. Articles for which new-drug approvals are now in effect should be covered by supplemental new-drug applications as necessary to provide for labeling revisions consistent with this policy statement.

§§ 250.103–250.104 [Reserved]

§ 250.105 Gelsemium-containing preparations regarded as prescription drugs.

It is the consensus of informed medical opinion that the margin of safety between the therapeutic and toxic concentration of gelsemium is narrow and it is difficult to predict the point at which the dose will be toxic. Very small doses may cause toxic symptoms. It is therefore the view of the Food and Drug Administration that gelsemium is not a proper ingredient in any product that is to be sold without prescription. Accordingly, any drug containing gelsemium will be regarded as misbranded under section 503(b)(4) of the Federal Food, Drug, and Cosmetic Act if its label fails to bear in a prominent and conspicuous fashion the statement “Caution: Federal law prohibits dispensing without prescription.”

EFFECTIVE DATE NOTE: At 67 FR 4906, Feb. 1, 2002, § 250.105 was amended in the last sentence by removing the phrase “‘Caution: Federal law prohibits dispensing without prescription.’” and by adding in its place the phrase “‘Rx only.’”, effective April 2, 2002.

§§ 250.106–250.107 [Reserved]

§ 250.108 Potassium permanganate preparations as prescription drugs.

(a) There have been a number of reports in the medical literature of serious injuries to women resulting from the misuse of potassium permanganate

in an effort to induce abortion. Reports from physicians who have treated such cases show that the injuries are commonly caused by introducing tablets or crystals of potassium permanganate into the vagina. Experience with these cases shows that such use of potassium permanganate is not effective in producing abortion, but that instead the drug produces serious and painful injury to the walls of the vagina, causing ulcers, massive hemorrhage, and infection. Such dangerous and useless employment of potassium permanganate is apparently encouraged among the misinformed by the mistaken idea that the vaginal bleeding caused by the corrosive action of the drug indicates a termination of pregnancy, which it does not.

(b) Potassium permanganate is a strong oxidizing agent, a highly caustic, tissue-destroying chemical, and a poison. There are no circumstances under which crystals and tablets of potassium permanganate constitute safe dosage forms for use in self-medication. It is the consensus of informed medical opinion that the only dosage forms of potassium permanganate known to be safe for use in self-medication are aqueous solutions containing not more than 0.04 percent potassium permanganate. Such solutions are safe for use in self-medication only by external application to the skin.

(c) In view of the very real potentiality for harmful effect, and the actual injuries caused by the misuse of potassium permanganate, the Food and Drug Administration believes that in order adequately to protect the public health:

(1) Potassium permanganate and potassium permanganate tablets intended for human use are drugs subject to section 503(b)(1) of the Federal Food, Drug, and Cosmetic Act and should be restricted to prescription sale. Such drugs will be regarded as misbranded if at any time prior to dispensing the label fails to bear the legend, “Caution: Federal law prohibits dispensing without prescription.”

(2) Potassium permanganate labeled for use as a prescription component in human drugs under the exemption provided in § 201.120 of this chapter or labeled for manufacturing use under the